ResQPOD

(Inspiratory Imependance Threshold Device)

Request for Trial Study Approval:

Use of ResQPOD

REQUEST FOR APPROVAL

Check One: ☐ **Local Optional Scope of Practice** ☒ **Trial Study**

EMS Medical Director: Dr. James Pointer, MD **Date:** 3/1/07

Local EMS Agency: Alameda County

Proposed Procedure or Medication: ResQPOD (Inspiratory Impedance threshold device)

Please provide the following information. For information provided, check "yes" and describe. For information not provided, check "no" and state the reason it is not provided.

Yes	No	
☑	☐	**1. Description of the procedure or medication requested:** ResQPoD - Inspiratory Impedance threshold valve device
☑	☐	**2. Description of the medical conditions for which the procedure/medication will be utilized:** Non-traumatic cardiac arrest in patients 12yrs. of age or older
☑	☐	**3. Alternatives (Please describe any alternate therapy[ies] considered for the same conditions and any advantages and disadvantages):** Conventional, manual CPR
☑	☐	**4. An estimate of frequency of utilization:** Approximately 150 + uses in a Six month period
☑	☐	**5. Other factors or exceptional circumstances:** Please see attached REQUEST FOR APPROVAL document for details

Please attach the following documents. Check "yes" for each document attached; for documents not attached, check "no" and state the reason it is not attached.

Yes	No	
☑	☐	**6. Any supporting data, including relevant studies and medical literature.** See attachment 1
		7. Recommended policies/procedures to be instituted regarding:
☑	☐	**Use** See attachment 2
☑	☐	**Medical Control** See attachment 2
☑	☐	**Treatment Protocols** See attachment 2
☑	☐	**Quality assurance of the procedure or medication** See attachment 2
☑	☐	**8. Description of the training and competency testing required to implement the procedure or medication.** See attachment 3
☑	☐	**9. Copy of the local EMS System Evaluation and Quality Improvement Program plan for this request.** See attachment 4

Form #EMSA-0391
Revised 03/18/03

NOTE: PLEASE SEE ATTACHED REQUEST FOR APPROVAL DOCUMENT FOR ADDITIONAL INFORMATION.

REQUEST FOR TRIAL STUDY APPROVAL

ALAMEDA COUNTY EMS AGENCY

With

ALAMEDA CONTY FIRE DEPARTMENT / HAYWARD FIRE DEPARTMENT

Proposed Trial Study

CONVETIONAL MANUAL CPR compared to CONVETIONAL MANUAL CPR with an IMPEDANCE THRESHOLD DEVICE (ResQPOD Circulatory Enhancer)

ANTICIPATED START DATE: APRIL 1, 2007

LOCAL EMS AGENCY: Alameda County Emergency Medical Services

PROVIDER AGENCY: Alameda County Fire Department / Hayward Fire Department

PROCEDURE / EQUIPMENT: Res Q POD Circulatory Enhancer

METHOD: Prospective Non-randomized (Conventional Manual CPR with ResQPOD) compared to Historic Controls / Database (Conventional Manual CPR)

1. Description of procedure, device or medication requested:

The ResQPOD Circulatory Enhancer is classified as an Inspiratory Impedance Threshold Device (ITD).

The ResQPOD is a valve device that is placed between the bag valve and mask of a BVM, between a bag valve and a tracheal tube, or between a bag valve and another rescue airway such as a Combitube. The device is intended to be used when performing CPR.

The ResQPOD utilizes the impedance of the body's respiratory and circulatory systems to create a vacuum (negative pressure) in the chest during the recoil phase of CPR, which follows each chest compression. The ResQPOD prevents the influx of respiratory gases into the chest during the chest wall recoil (relaxation or decompression phase), which lowers the intrathoracic pressure and draws more venous blood back to the heart. Improved blood return to the right side of the heart (preload) results in improved blood flow to the lungs, and out of the left side of the heart (cardiac output) during subsequent compressions.

2. Description of the medical conditions for which the procedure / medication / device will be utilized:

The Alameda County Fire Department and Hayward Fire Department Paramedics will provide conventional CPR with the ResQPOD to **ALL non-traumatic cardiopulmonary arrest patients that are presumed to be 12 years of age or older.** All patients must meet Alameda County criteria for resuscitation efforts. Special attention will be directed to meeting the current 2005 American Heart Association standards for number and volume of ventilations and number and depth of chest compressions for CPR. The Auto Pulse or any other CPR adjuncts will **not** be used for the study patients.

Paramedics will intubate the cardiac arrest patient as per Alameda County protocol. Intubations will be confirmed by colorimetric capnometer or waveform capnography, and the esophageal detection device. Medics will perform conventional CPR according to current 2005 AHA Guidelines and will attach the ResQPOD circulatory enhancement device between the bag valve and mask, bag valve and tracheal tube or bag valve and Combitube.

3. Alternatives (disadvantages / disadvantages)

There is one alternative to the proposed Impedance Threshold Device (ResQPOD): conventional manual CPR.

Conventional Manual CPR:

- Advantages = none
- Disadvantages = lower blood flow, lower perfusion pressures

4. An estimate of frequency of utilization:

The Alameda County Fire Department attempts resuscitation on approximately 200+ medical cardiopulmonary arrests per year. The Hayward Fire Department attempts resuscitation on approximately 100+ non-traumatic cardiopulmonary arrests per year. Combined, the two departments, over a six month period should utilize the ResQPOD approximately 150 times. The non-traumatic cardiac arrest survival rates for Alameda County and Hayward Fire Departments collectively, and specifically regarding ventricular fibrillation / pulseless ventricular tachycardia are: 2005 = 13.1%, and 2006 = 15.0%.

5. Other factors or exceptional circumstances:

The following are contraindications for the use of the ResQPOD:
Dilated cardio myopathy, congestive heart failure, pulmonary hypertension, flail chest, aortic stenosis, chest pain, shortness of breath. Obviously, the patients may not be able to provide a history of these conditions. The device should not be used if family members or friends provide a history of any of the above conditions. The device should be removed upon the return of spontaneous circulation (ROSC). While it is probably acceptable for breathing patients, it is not designed to do so. The device may / should be reapplied if the patient subsequently loses pulses.

6. Any supporting data, including relevant studies and medical literature:

See attachment **#1** for documentation

7. Recommended policies / procedures to be instituted regarding: See attachment **#2** for documentation

- **Use:** (Protocol)
- **Medical Control:** (Protocol)
- **Treatment Protocols:** (Protocol)

- **Quality assurance of procedure / medication / device:** (Protocol)

Each Fire Department will complete a data summery sheet with the following data points: estimated downtime, estimated time to CPR, estimated time to defibrillation (if applicable), initial rhythm, changes in rhythm, initial colorimetric capnomety or capnography values and any changes in the course of the cardiac arrest, return of spontaneous circulation (ROSC) at scene, ROSC at hospital, and survival to discharge from hospital; this will be obtained by the EMS agency monthly. See attached documentation (Data sheet)

8. Description of the training and competency testing required to implement the procedure / medication / device: See attachment **#3** for documentation (protocol and training materials)

9. Copy of the local EMS System Evaluation and Quality Improvement Program plan for this request: See attachment **#4** for documentation

The ResQPOD trial study will be reviewed and evaluated by following applicable Administrative policies under Section 1000 and Policy # 2251 established by Alameda County Emergency Medical Services: (ALCO EMS Administrative Manual / Policies)

- Trail Study Process (Admin. # 1000)
- Emergency Medical Oversight Committee (EMOC) (Admin. # 1000)
- Research Committee (Admin. # 1000)
- Quality Council (QC) (Admin. # 1000)
- Quality Improvement Responsibilities – EMS (QIR # 2250 / 2251)

Please refer to the attached ResQPOD Protocol for specifics regarding process, procedure, data collection and medical oversight.

ADVANCED CIRCULATORY SYSTEMS, INC.

ResQPOD Circulatory Enhancer ®

Circulatory Enhancer Technology Overview

ResQPOD Circulatory Enhancer

- Product Features
- Technology
- FAQs
- Published Articles
- Clinical Information
- American Heart Association Guidelines
- Circulatory Enhancement Applications
  - Sudden Cardiac Arrest
  - Hypotension
  - Blood Loss
- Instructions for Use
- Product Literature and Video

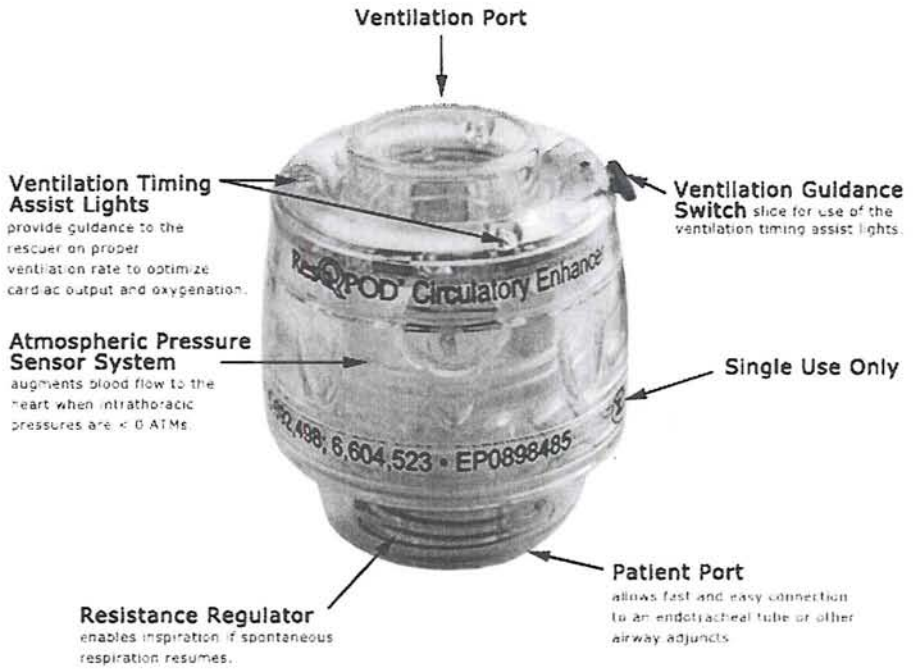
ACSI Circulatory Enhancer

Home

Advanced Circulatory Systems, Inc.
7615 Golden Triangle Drive,
Suite A
Eden Prairie, MN 55344
877-RESQPOD
1-877-737-7763
www.advancedcirculatory.com

Product Features

The ResQPOD is placed between a ventilation source (e.g., bag-valve or demand-valve resuscitator) and an airway adjunct. The ResQPOD is designed with a series of features to aid rescuers in enhancing circulation for patients receiving assisted ventilation, such as those receiving CPR.



The generally cleared indication for the ResQPOD is a temporary increase in blood circulation during emergency care, hospital, clinic and home use. Click here to review the Instructions for Use. Studies are ongoing in the United States to evaluate the long-term benefit of the ResQPOD for indications related to patients suffering from cardiac arrest, hypotension during dialysis and severe blood loss.

For more information on completed clinical studies click here. The references on this website are not intended to imply specific outcome-based claims not yet cleared by the US Food and Drug Administration.

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Introducing the most advanced device for enhancing circulation in patients requiring assisted ventilation, such as those receiving Cardiopulmonary Resuscitation (CPR)

The ResQPOD Circulatory Enhancer

- Increases blood flow to the heart and brain during assisted ventilation
- Increases the opportunity for survival and normal neurological outcome
- Is effective with standard CPR or other methods of CPR (i.e., active compression decompression - ACD)
- Works in conjunction with all standard resuscitation techniques and equipment
- Recommended as a circulatory enhancer for the treatment of cardiac arrest by the AHA.

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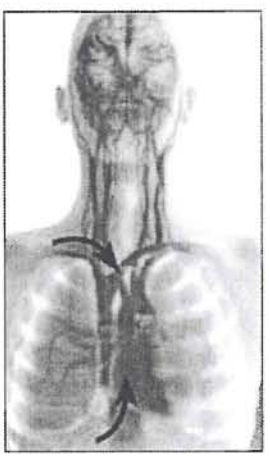
Technology

The ResQPOD's selective inspiratory technology for patients receiving assisted ventilation, for example, during the release phase of CPR.

- Utilizes the relationship of the respiratory and circulatory systems.
- Selectively impedes inspiratory gases from coming into the lungs for patients receiving assisted ventilation, for example, during the release phase of CPR.
- Results in increasing negative pressure and creating a greater vacuum in the chest, and
- Results in greater venous return.

Increasing Blood Flow During Assisted Ventilation
During the decompression (release) phase of CPR, for example, an increase in negative pressure in the thoracic cavity results in drawing more blood back into the chest, providing greater venous return to the heart.

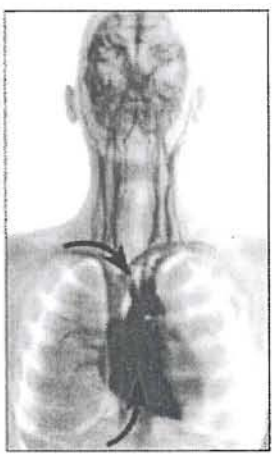
CPR Alone



Blood Flow to Heart

RELEASE: CPR alone delivers approximately 15% of normal blood flow to the heart

ResQPOD + CPR

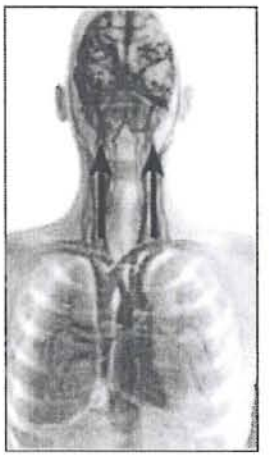


Greater Blood Flow to Heart

RELEASE: ResQPOD doubles blood flow back to the heart

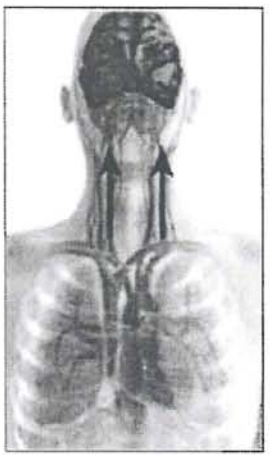
Improved venous return results in increased cardiac output during the subsequent compression phase of CPR, providing greater blood flow to the brain.

CPR Alone **ResQPOD + CPR**



Blood Flow to Brain

COMPRESSION: CPR alone delivers approximately 25% of normal blood flow to the brain



Greater Blood Flow to Brain

COMPRESSION: ResQPOD delivers >70% of normal blood flow to the brain

The ResQPOD selectively impedes inspiratory gases during the release phase of CPR resulting in:

- Increased negative pressure in the thorax
- Greater venous return to the heart
- Increased coronary perfusion
- Increased blood flow during the next compression

- Resuscitation 2002; Langhelle et al
- Anesthesia and Analgesia 2001; Lurie et al

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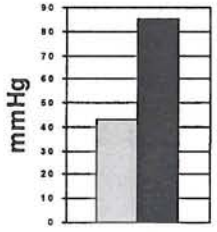
Performing Optimal CPR

1. Begin using the ResQPOD and performing chest compressions as soon as cardiac arrest is confirmed. Do not delay chest compressions!
2. Remove the ResQPOD if a pulse returns.
3. Ventilate over 1 second (until chest rises) with both secured and unsecured airways; do not hyperventilate!

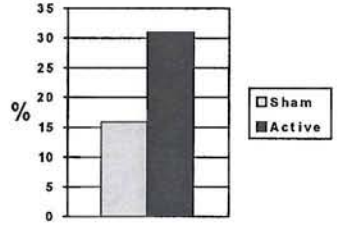
4. Assure that the chest wall recoils completely after each compression.
5. Provide chest compressions at a depth of 1.5 - 2" and a rate of 100/min. Timing assist lights can be used to guide the chest compression/release rate: 100/min = 10 compressions/light flash.
6. Avoid unnecessary delays or interruptions in chest compressions.
7. Remove secretions from ResQPOD by shaking or blowing out with the ventilation source.

Clinical Data

The ResQPOD, or an earlier version of the ITD, has been evaluated in over 10 animal and 7 clinical studies (www.advancedcirculatory.com). These studies have shown that the ResQPOD doubles blood flow to the heart and brain, and significantly increases circulation and survival in out-of-hospital cardiac arrest. In a Milwaukee (WI) study of cardiac arrest patients undergoing conventional CPR, systolic blood pressure and 24-hour survival rates in patients presenting in a rhythm other than asystole almost doubled when an active (functional) ITD was used compared to a sham (placebo) ITD ($p<0.05$ for both).



Systolic BP after 14 minutes of ITD use[1]



Survival to 24 Hours[2]

[1]Pirrallo et al. Effect of an inspiratory ITD on hemodynamics during conventional manual CPR. *Resuscitation* 2005;66:13-20.
[2]Aufderheide et al. Clinical evaluation of an inspiratory ITD during standard CPR in patients with out-of-hospital cardiac arrest. Crit Care Med 2005;33(4):734-40.

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49-0336-000, 02

ResQPOD®

Circulatory Enhancer

Strengthening the Chain of Survival

An impedance threshold device is recommended in the 2005 AHA guidelines as the only Class IIa CPR device to improve hemodynamics and increase the return of spontaneous circulation during cardiac arrest

ADVANCED CIRCULATORY SYSTEMS, INC.

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ResQPOD® Circulatory Enhancer

The ResQPOD is an impedance threshold device that provides Perfusion on Demand by regulating pressures in the thorax during states of hypotension.

Animal and clinical studies have shown that during CPR, the ResQPOD:

- Doubles blood flow to the heart
- Increases blood flow to the brain by 50%
- Doubles systolic blood pressure
- Increases survival rates
- Increases the likelihood of successful defibrillation
- Provides benefit in all arrest rhythms
- Circulates drugs more effectively

The American Heart Association, in their 2005 Guidelines, gave an impedance threshold device (e.g. ResQPOD) a Class IIa recommendation to increase blood flow and immediate survival rates in patients in cardiac arrest. It is the most highly recommended CPR adjunct in the new Guidelines and carries a higher recommendation than any medication used to increase circulation in adults in cardiac arrest. The ResQPOD is the only impedance threshold device on the market.

The ResQPOD is easy to use. It provides a unique way to increase circulation during CPR by refilling the heart after each chest compression. In addition, timing assist lights on the ResQPOD help provide guidance on the proper compression and ventilation rates.

How it Works

The ResQPOD prevents unnecessary air from entering the chest during CPR. When air is prevented from rushing into the lungs as the chest wall recoils, the vacuum (negative pressure) in the thorax is greater. This enhanced vacuum pulls more blood back to the heart, doubling blood flow during CPR. Studies have shown that this mechanism increases cardiac output, blood pressure and survival rates. Patient ventilation and exhalation are not restricted in any way.

Using the ResQPOD on a Facemask

1. Connect ResQPOD to facemask.
2. Open airway. Establish and maintain tight face seal with mask throughout chest compressions; a head strap or 2-handed technique is recommended.
3. Connect ventilation source to ResQPOD, or mouthpiece if performing mouth to mask ventilation.
4. Perform CPR @ recommended compression to ventilation ratio.

Mouth to Mask

Using the ResQPOD on an ET Tube

1. Confirm ET tube placement and secure with commercial tube restraint.
2. Connect ResQPOD to ET tube.
3. Connect ventilation source to ResQPOD.
4. Perform continuous chest compressions.
5. Remove clear tab and turn on timing assist lights. Ventilate asynchronously @ timing light flash rate of 10/min.
6. Administer ET meds directly into ET tube.
7. Place $ETCO_2$ detector between ResQPOD and ventilation source.